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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,378	02/18/2004	Bruce K. Redding JR.	04-40080-US (879388.20001	3551

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EXAMINER	
GRAY, PHILLIP A	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,378	REDDING, BRUCE K.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to applicant's communication filed on 1/18/2007. Currently amended and newly added claims 1-20 are pending and rejected.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. Patent 6,392,327) in view of Nagar et al. (U.S. Patent Number 6,846,288).

Lewis discloses a sonic transducer and feedback control method to provide an ultrasonic output transducer for imaging, medical therapy, motors, and sonar systems. Lewis discloses an apparatus suitable for transdermal substance delivery comprising at least one ultrasonic transducer (12), which generates an ultrasonic transmission, and at least one sensor (20) with at least one transducer to sense reflected ultrasonic transmission (see paragraphs 4 through 6), along with a control device (14). It is noted that the disclosed Lewis apparatus is capable of meeting the functional use recitation of claim 1, thereby Lewis could be used to sense ultrasonic transmissions indicative of substances or drugs moved through tissue or another medium.

Nagar et al. discloses and teaches a photoacoustic assay and imaging system which includes a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances, and the reflected ultrasonic transmission received by the sensor is indicative of substances actually moved into said tissue (see abstract and paragraphs at column 2 line 24 through column 6 line 62, and sensor 26 for example).

Lewis discloses the claimed invention except for the a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances, and the reflected ultrasonic transmission received by the sensor is indicative of substances actually moved into said tissue. Nagar teaches that it is known to use a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances (as set forth in

paragraphs at column 13 line 62 through column 14 line 64) to provide a means of assaying a component of a localized region of interest in a body and localizing and sensing changes within an area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivery device as taught by Lewis with a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances, and the reflected ultrasonic transmission received by the sensor is indicative of substances actually moved into said tissue, as taught by Nagar, since such a modification would provide the delivery device with a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances for providing a means of assaying a component of a localized region of interest in a body and localizing and sensing changes within an area.

Claims 10, 18, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Jackson et al. (U.S. Patent 6,475,148) in view of Nagar et al. (U.S. Patent Number 6,846,288). Jackson discloses a method for ultrasonic transdermal delivery. The Jackson method relates generally to using ultrasound for delivery of drugs from microspheres. In Jackson, diagnostic medical ultrasound imaging was used to image microspheres and destroy them with acoustic energy. The destruction of the microspheres was optimized such that subsequent imaging showed an inflow or wash-in of new microspheres into the image region or provided a loss of correlation (see column 1, line 28). This method includes a transducer generated ultrasonic transmission for inducing substance movement, a sensor that senses substance

movement from reflected ultrasonic transmissions, and a control device (columns 2 through 4).

Jackson discloses the claimed invention except for the a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances, and the reflected ultrasonic transmission received by the sensor is indicative of substances actually moved into said tissue. Nagar teaches that it is known to use a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances (as set forth in paragraphs at column 13 line 62 through column 14 line 64) to provide a means of assaying a component of a localized region of interest in a body and localizing and sensing changes within an area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivery device as taught by Jackson with a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances, and the reflected ultrasonic transmission received by the sensor is indicative of substances actually moved into said tissue, as taught by Nagar, since such a modification would provide the delivery device with a sensor positioned to receive ultrasonic transmissions reflected from tissue or substances for providing a means of assaying a component of a localized region of interest in a body and localizing and sensing changes within an area.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis in view of Nagar, in further view of Shimada et al. (U.S. Patent number 5,267,985). Lewis discloses the claimed invention except for the ultrasound frequency transmission in the range of about 20 KHz to 30 MHz. Shimada teaches that it is known to use ultrasound

frequency transmissions in the range of 1hz to 100 MHz for therapeutic or diagnostic ultrasound, (as set forth in Column 5,Line 39 through Column 7, Line 13) to provide "optimum diffusion of the drug across the stratum corneum while maximizing penetration of a drug or other substance into the local area of target tissue". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer as taught by Lewis to operate in a 1hz to 100 MHz frequency range as taught by Shimada, since such a modification would provide the ultrasonic transducer with a 1hz to 100 MHz frequency range to provide for effective and efficient diffusion of drugs into a given tissue.

Claims 3 through 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis in view of Nagar in further view of Dellagatta (U.S. Patent number 5,954,675). Lewis discloses the claimed invention except for the ultrasonic intensity range and alternating, pulsed, or continuous waveform. Dellagatta teaches that it is known to use an ultrasonic intensity range up to 3.0 W/sq. cm. (Column 3, Line 7) to foster hydration of the stratum corneum (Column 3, Line 47). It would have been obvious of one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer as taught by Lewis in view of Nagar with a 0 to 3.0 W/sq. cm. intensity range as taught by Dellagatta, since such a modification would provide the ultrasonic transducer with a 0 to 3.0 W/sq. cm. Ultrasonic transmission intensity range for providing hydration of the tissue that is receiving the ultrasonic signals.

Further Dellagatta discloses that it is known to use an alternating, pulsed or continuous waveform (Column 1, Line 14) as a preferred treatment where heat exacerbates pain in the patient, or when only non-thermal, mechanical effects of ultrasound, e.g. enhancement of tissue regeneration, are desired. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer's waveform as taught by Lewis in view of Nagar with an alternating, pulsed, or continuous waveform as taught by Dellagatta, since such a modification would provide the transducer's waveform with and alternating, pulsed, or continuous waveform, for providing treatment without heat and a mechanical therapy for pain management and tissue regeneration.

It is noted that Lewis in view of Nagar in further view of Dellagatta discloses the claimed invention except for specifically referencing a "sawtooth" waveform or a "square" waveform. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the alternating waveform produced by the ultrasonic transducer included both "square" or "sawtooth" waveforms, since it was known in the art that "square" or "sawtooth" waveforms are typical types of alternating waveforms for enhanced measured efficient ultrasonic transmission delivery.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (6,475,148) in view of Nagar in further view of Shimada (5,267,985). Jackson discloses the claimed method except for the ultrasound frequency transmission in the range of about 20 KHz to 30 MHz. Shimada teaches that it is known to use ultrasound frequency transmissions in the range of 1hz to 100 MHz for therapeutic or diagnostic ultrasound,

(as set forth in Column 5,Line 39 through Column 7, Line 13) to provide "optimum diffusion of the drug across the stratum corneum while maximizing penetration of a drug or other substance into the local area of target tissue". It would have been obvious to one having ordinary skill in the art at the time the method was made to modify the transdermal substance delivery method as taught by Jackson in view of Nagar to operate in a 1hz to 100 MHz frequency range as taught by Shimada, since such a modification would provide the transdermal substance delivery method with a 1hz to 100 MHz frequency range to provide for effective and efficient diffusion of drugs into a given tissue.

Claims 12 through 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Nagar in further view of Dellagatta (5,954,675). Jackson in view of Nagar discloses the claimed method except for the ultrasonic intensity range and alternating, pulsed, or continuous waveform. Dellagatta teaches that it is known to use an ultrasonic intensity range up to 3.0 W/sq. cm. (Column 3, Line 7) to foster hydration of the stratum corneum (Column 3, Line 47). It would have been obvious of one having ordinary skill in the art at the time the invention was made to modify the transdermal drug delivery method as taught by Jackson in view of Nagar with a 0 to 3.0 W/sq. cm. intensity range as taught by Dellagatta, since such a modification would provide the transdermal drug delivery method with a 0 to 3.0 W/sq. cm. Ultrasonic transmission intensity range for providing hydration of the tissue that is receiving the ultrasonic signals.

Further Dellagatta discloses that it is known to use an alternating, pulsed or continuous waveform (Column 1, Line 14) as a preferred treatment where heat exacerbates pain in the patient, or when only non-thermal, mechanical effects of ultrasound, e.g. enhancement of tissue regeneration, are desired. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the transdermal delivery method as taught by Jackson in view of Nagar with an alternating, pulsed, or continuous waveform as taught by Dellagatta, since such a modification would provide the transdermal delivery method with and alternating, pulsed, or continuous waveform, for providing treatment without heat and a mechanical therapy for pain management and tissue regeneration.

It is noted that Jackson in view of Nagar in further view of Dellagatta discloses the claimed invention except for specifically referencing a "sawtooth" waveform or a "square" waveform. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the alternating waveform produced by the method's ultrasonic transducer included both "square" or "sawtooth" waveforms, since it was known in the art that "square" or "sawtooth" waveforms are typical types of alternating waveforms for enhanced measured efficient ultrasonic transmission delivery.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Number 5,445,611, Eppstein et al. discloses a method and apparatus for Enhancement of transdermal delivery with ultrasound and chemical enhancers

U.S. Patent Number 6,041,253, Kost et al. discloses a method and apparatus for effect of electrical field and ultrasound for transdermal drug delivery.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER